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Guidance for the Reregistration of
Pesticide Products Containing Zinc
Phosphide as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE
PRODUCTS CONTAINING ZINC PHOSPHIDE
AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

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I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute such product in commerce, must apply for reregistration.

A new review procedure has been developed. Under it, EPA publishes Guidance Documents, each of which discusses a particular pesticide active ingredient. Each Guidance Document summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have; compliance with standards of toxicity, composition, labeling, and packages; and satisfaction of the compensation provisions of FIFRA Section 3(c)(1)(D).

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product, if the registrant fails to comply with the procedures for reregistration set forth in this Guidance Document.

This Guidance Document has been prepared to provide you, the registrant, with specific information on how you may maintain the effect your current registration(s). (Refer to the cover letter's attachment for a listing of your affected products.) If for any reasons you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

II. REGULATORY POSITION AND RATIONALE

- A. Introduction
- B. Use Profile
- C. Regulatory Position
- D. Regulatory Rationale
- E. Criteria for Registration Under the Standard
- F. Acceptable Ranges and Limits
- G. Required Labeling
- H. Tolerance Reassessment

A. INTRODUCTION

The Agency's regulatory position, described in this chapter, is based on an evaluation of all registered products containing zinc phosphide as the sole active ingredient. The Agency has also incorporated relevant information contained in the Aluminum Phosphide Registration Standard (October, 1981). This chapter also presents the rationale for our position and the criteria for registration and reregistration. A discussion of labeling requirements and a reassessment of tolerances are also presented in this chapter. The regulatory position considers intrastate and 24(c) (Special Local Need) registrations, as well as products federally registered under section 3 of FIFRA.

B. USE PROFILE

Zinc phosphide is used as a bait to control numerous mammals (primarily rodents) in various application sites including orchards, vineyards, sugarcane, rangelands, agricultural premises, aquatic areas, commercial establishments, public areas (such as parks), dumps, noncrop areas, and homes. It derives its action by the liberation of phosphine in the gastrointestinal tract of the target organism.

Zinc phosphide is registered as technical and intermediate formulations (to 94% a.i.), concentrates (to 94% a.i.) and baits (0.5 to 2% a.i.) and tracking powders (10% a.i.). The formulated baits for domestic use and nondomestic uses in and around buildings are unrestricted. All dry formulations of 60% a.i. and greater are restricted for use only by certified applicators or by persons under their direct supervision. All bait formulations for nondomestic uses and all dry formulations of 10% a.i. or greater uses around the home are also restricted.

Tolerances have been established (40 CFR 180.234) for residues of phosphine resulting from the use of zinc phosphide bait in or on three raw agricultural commodities. For grasses, the tolerance is 0.1 ppm and for grapes and sugarcane the tolerance is 0.01 ppm. These are based on the lower label application rates and studies which indicate the dissipation or conversion of the zinc phosphide into innocuous phosphates. Although some labels permit the use of baits in or around food handling facilities, the use directions preclude contaminating food or food processing equipment. Safe reentry is to be controlled by the applicator who is required to secure the application sites, remove unused baits and/or allow entry only when the bait materials have dissipated to safe levels.

C. REGULATORY POSITION

Based on its review and evaluation of the available data and other relevant information on zinc phosphide, the Agency has made the following determinations:

1. Rodenticide products containing zinc phosphide as the sole active ingredient may be registered for sale, distribution, and use, subject to the terms and conditions specified in this standard.
2. None of the risk criteria in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded by the uses of zinc phosphide specified in this standard.
3. The registrant must provide or agree to develop additional data, specified in Chapter III, to maintain the existing registration or to permit new registrations.
4. Tolerances for registered uses in or on rangeland grasses, vineyards, and sugarcane fields are supported by residue and toxicology data. In the registration standard for aluminum phosphide, data have been requested on the nature of the toxicological significance of uncharacterized residues. Examination of these data will determine if the data used to establish tolerances for zinc phosphide residues are adequate. Tolerances have not been established for any other uses. Applicants seeking registration of zinc phosphide products for use on other sites which could result in residues on food or feed must include data for either establishing a tolerance or justifying an exemption from a tolerance, or include data showing that residues will not be present.

D. REGULATORY RATIONALE

The Agency has concluded that registration for zinc phosphide should continue for the following reasons:

1. Zinc phosphide is classified as a restricted use rodenticide, used in bait for controlling mammals, primarily field rodents, and as a tracking powder for controlling rodents indoors. The only general use registrations are for ready-to-use formulations with 2% or less a.i. zinc phosphide, applied in or around buildings.
2. Because of the restricted use classification for the major use patterns, exposure will be limited to certified professional applicators. Labeling required by this standard includes use precautions to prevent acute oral, dermal, inhalation and eye hazards.
3. No chronic or subchronic toxicological hazards of immediate concern have been identified. Neither repeated exposure nor significant residues are expected in food or feed items.

4. The major known risk from zinc phosphide to nontarget wildlife results from ingestion of treated bait. Adherence to labeling requirements specified in this chapter will partially reduce the exposure to fish, birds, and mammals, particularly endangered species.

The Agency has requested data on the unidentified residues resulting from the use of aluminum phosphide. This information will be evaluated for zinc phosphide also. If the Agency concludes, when these residues are chemically characterized, that they are toxicologically insignificant, the requirement for chronic feeding, oncogenic, metabolism, and reproduction studies will be waived. If no determination can be made that these unidentified residues are toxicologically insignificant, the Agency may require chronic feeding, oncogenic, metabolism, and reproduction studies.

5. The review of the available data has not revealed any risks sufficient to initiate a Rebuttable Presumption Against Registration.
6. The Pesticide Incident Monitoring Systems data indicate that accidents involving zinc phosphide resulted from misuse of registered products.
7. In accordance with FIFRA, the Agency's policy is not to cancel or to withhold registration merely for the lack of data. (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA.) Rather, publication of the standard provided a mechanism for identifying data needs, and registration under the standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

E. CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be subject to this standard, products must meet the following conditions:

- contain zinc phosphide as the sole active ingredient;
- conform to the acute toxicity limits, product composition and use pattern requirements stated in Section F, below;
- bear the required labeling stated in Section G, below.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in this standard including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offer to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136a (c)(1)(D). Applicants for registration under this standard must contact the Registration Division for specified instructions, companies whose data must be cited, and to whom compensation must be offered.

F. ACCEPTABLE RANGES AND LIMITS

1. Manufacturing-Use Products

a. Product Composition Standard

To be covered under this standard, manufacturing-use products must contain 94% or less zinc phosphide as the sole active ingredient. The composition of each formulation proposed for registration must be fully described within an appropriate certification of limits.

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing zinc phosphide, regardless of the acute toxicity category, provided that the labeling of such products bears appropriate precautionary statements.

c. Use Patterns

To be registered under this standard, manufacturing-use products containing zinc phosphide must be labeled for formulation only into end-use rodenticide products for use on rangelands, orchards, vineyards, sugarcane fields, or for use in and around buildings and homes, dumps, noncrop areas, and aquatic areas.

2. End-Use Products

a. Product Composition Standard

To be registered under this standard, end-use products must be one of the following:

1. Tracking powder containing 10% phosphide
2. Bait, pellet, or tablet containing 2% or less zinc phosphide
3. Concentrate of 984% or less zinc phosphide to be used to prepare baits of 2% or less zinc phosphide

b. Acute Toxicity Limit

The Agency will consider, for registration, end-use products of any acute toxicity category. This acceptance, however, is predicated upon appropriate precautionary labeling.

c. Use Patterns and Application Methods

To be registered under this standard, end-use products containing zinc phosphide formulated as a pellet, tablet, or bait, must be labeled as a rodenticide for one or more of the following uses:

1. For spot treatment around burrows in orchards, vineyards, and sugarcane fields and on rangelands and noncrop areas;
2. For broadcast by ground spreader or aircraft in orchards, vineyards, and sugarcane fields and on noncrop areas;
3. For use in tamper-proof containers or rafts and/or bait boards on noncrop aquatic areas;
4. For spot treatment in and around buildings.

Products formulated as a tracking powder must be labeled as a rodenticide for use indoors.

G. REQUIRED LABELING

1. General

All manufacturing-use and end-use products containing zinc phosphide must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package portion of this standard contains specific information regarding label requirements.

The following first aid information must appear on all labels:

Statement of Practical Treatment

Any persons applying zinc phosphide products and experiencing signs and symptoms such as nausea, abdominal pain, tightness in the chest, or weakness should be seen by a physician immediately.

If swallowed, drink 1-2 glasses of water and induce vomiting and by touching the back of the throat with the finger. Avoid the use of all oils. Have person lie down and keep warm. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin or eyes, flush with plenty of water.

2. Human and Domestic Animal Statements

Required labeling for all concentrates and tracking powders follows.

- Do not ingest, or allow to come in direct skin or eye contact, and do not inhale. May be harmful or fatal if swallowed. Wash hands thoroughly with soap and water after use.
- Use rubber gloves if contact with skin may occur when mixing or placing baits.
- Wash all utensils, spoons or measuring devices thoroughly after using.

- Store in a dry place, Do not store around the home.
- Dispose of pesticide and containers in accordance with the most recent statements.

Required labeling for all concentrates follows.

- Bait materials resembling human food must be altered in form by crushing, balling, dicing or pelleting so that they are not readily recognized as food.
- Keep products away from children, irresponsible individuals, domestic animals, pets, and poultry.
- Use concentrates for making baits in open areas, especially if the baiting materials are wet. Do not breathe dry baits; use respiratory protection when mixing baits.
- Place baits in locations not accessible to children, pets, livestock and nontarget wildlife, or use tamper-proof bait boxes for products used in and around buildings.
- Meat and fish bait must be placed in tamper-proof bait boxes or deeply into rat burrows because dogs and cats will actively search them out.
- Do not re-treat the same area with zinc phosphide at less than 30-day intervals.
- Collect and properly dispose of uneaten bait and dead rodents after completion of the control program, often set at 72 hours.
- Do not exceed application rates specified on label.

Required labeling for tracking powders follows.

- Sprinkle along walls, in corners and concealed places where mice travel. Do not place where exposure to moisture or acidity could occur.
- Do not place powder near ventilation duct openings.
- Maintain dusted area for at least 20 days (do not repeat within 30 days).
- Do not place powder where the possibility exists of contaminating foods or surfaces which come in contact with foods.

3. Environmental Hazard Statements (baits, pellets, tablets.)

All labels should be correct with regard to target species. The acceptable scientific and common names for the target species should be used. The following are required general labeling.

- This product is toxic to wildlife and fish. Birds and other wildlife feeding on treated bait may be killed.
- Do not apply to open ground, roads and areas in which no vegetation occurs. Pick up and properly dispose of all spilled toxic bait.
- Keep out of lakes, streams, ponds and all aquatic systems. Do not apply where runoff from this product will enter an aquatic system.
- Check for and dispose of excess or spilled bait and carcasses daily until the baits are expended or are removed.

The following labeling is required for endangered species considerations.

Whooping Crane (Grus americana)

Do not use this product 30 days prior to arrival and 30 days after the whooping crane leaves known crane habitat.

Attwater's greater prairie chicken (Tympanuchos cupido attwater)

Do not use this product in the presently occupied range of the Attwater greater prairie chicken in the following Texas counties: Aransas, Austin, Brazoria, Colorado, Dewitt, Fort Bend, Galveston, Goliad, Harris, Refugio, Victoria, Waller, and Wharton.

Yellow-shouldered Black bird (Agelaius xanthomus) and Puerto Rican Plain Pigeon (Columba inornata wetmorel)

This product must not be used in the following areas except in tamperproof bait boxes (within 10 kilometers of central Aquirre, Lago Ciara, Ceiba, San German; 15 kilometers of La Esperanza; south of Highway 2 from city of Mayaguez to the city of Ponce and all of Mona Island, Puerto Rico).

Utah prairie Dog (Cynomys parvidens)

Do not use this product in the range of the Utah Prairie dog (Utah).

Salt marsh harvest mouse (Reithrodontomys ravirentis)

Do not use this product within 1/2 mile of salt marsh vegetation and/or brackish water wetlands which are located 1) near or adjacent to San Pablo Bay and San Francisco Bay, or 2) in the Sacramento River below or adjacent to the confluence of the Sacramento River and the San Joaquin River (California).

Morro Bay Kangaroo Rat (*Dipodomys heermanni morroensis*)

Do not use this product within 2 1/2 miles of Baywood Park which is located on Morro Bay (California).

Aleutian Canada goose (*Branta canadensis leucoparia*)

Do not use this product from October to March in the Federally closed goose hunting areas in the state of California. See current Duck and Goose Hunting game laws from current map.

The appropriate labeling requirement will depend upon the use site and its geographic location. If the label restricts the product to use in a state east of the Mississippi River, then none of the above Endangered Species considerations will be required.

If products are labeled for use on rangelands, on grasslands, and on agricultural areas and/or labeled for use in and around marshes that would allow zinc phosphide to be used west of the Mississippi River and east of the eastern state lines of Washington, Oregon and California, they will be required to place on their labels endangered species considerations for the whooping crane.

If the label is national and U.S. territorial in scope and has field uses, all eight species and their respective statements are required.

If the label allows the product to be used in the following states or territories at the listed site or a closely related site, then the endangered species of concern and its respective labeling statement will be required.

<u>State/U.S. Territory</u>	<u>Use Sites</u>	<u>Endangered Species of Concern</u>
California	Levees; marshes; rights of way	Salt Marsh Harvest Mouse
	Rangeland; parks; housing areas	Morro Bay Kangaroo Rat
	Agricultural areas	Aleutian Canada Goose
Texas	Rangeland; grassland; agricultural areas	Attwater's Greater Prairie Chicken
Utah	Rangeland; agricultural areas	Utah Prairie Dog
Puerto Rico	Agricultural area	Puerto Rican Plain Pigeon and Yellow-shouldered Blackbird

4. Site Specific Labeling

General warnings and limitations required for all agricultural crops:

This bait must not be applied on roads, near residential area, or over water. Do not broadcast over growing crops other than sugarcane. Apply bait on warm, clear days. Do not graze animals in treated areas.

a. Orchards

Bait applications should be made immediately after harvest and before leaf fall, when the grass is not yet matted.

b. Orchards and Vineyards

Do not make broadcast application of bait over growing crops when the bait may lodge on the plant. Do not apply to bare ground.

c. Sugarcane

Bait material must not be applied to sugarcane which is less than 6 months of age, nor within 90 days of harvest. For a 36 month crop period, the total number of bait (2%) applications must not exceed four, and the total bait applied shall not exceed 20 pounds per acre (0.4 lb zinc phosphide).

G. TOLERANCE REASSESSMENT

As a rodenticide bait with use limited mainly to certified applicators, zinc phosphide has been accepted principally for rodent control in orchards, vineyards, and sugarcane fields. Data reviewed for this standard include studies indicating residues resulting from these applications will not exceed the tolerances established for residues of phosphide [i.e., 0.01 ppm on grapes and sugarcane, 0.1 ppm in or on grasses (rangeland)]. Tolerances have not been established by Canada or CODEX.

As a result of the established tolerances for zinc phosphide, the theoretical human dietary exposure to phosphine is calculated to be 0.0006 mg/day (TMRC). An acceptable daily intake (ADI) has not been established for either zinc phosphide or for phosphine.

Other sections of this guidance package provides additional information and instructions regarding tolerance reassessment and labeling.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

- A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D).
- B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:
 1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing-Use and End-Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product (taking into account your product's composition and formulation category, and the uses of your product which its label will permit).
 2. The "product-specific" data" which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).
- C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:
 1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product-specific data upon which approval of your application will be based, except that:
 - a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.
 - b. FIFRA Section 3(c)(2)(D) provides that you need not furnish an offer with respect to any "generic" data, if your product is an end-use product and if its active ingredient will be present in your product solely because of the incorporation into your product of another registered manufacturing-use product which contains that active ingredient and which you purchase from another producer.

* Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

Note: This exemption does not cover "product-specific" data.

- c. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Table A, B, or C. You will be required to write those companies if the data in those tables are required to support your formulations and uses.
 - d. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.
 - e. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.
2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:
- a. A notification of your intent to apply for reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.
 - b. An offer to pay the person compensation, with respect to approval of your application, to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.
 - c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

- A. This portion of the Guidance Document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this Guidance Document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

- B. Entitlement of Certain End-Use Registrants to an Exemption. Under the circumstances described in this Section III(B), EPA will refrain from suspending the registration of an end-use product even if its registrant does not submit data in response to this Notice. EPA's position is based on the intent of Congress as set forth in FIFRA Section 3(c)(2)(D). Under that section, if generic data on an active ingredient had already been submitted to EPA, an applicant for registration of an end-use product would be excused from the normal Section 3(c)(1)(D) requirement of submitting or citing, and offering to pay compensation for, those data as a condition of obtaining registration. To qualify for that exemption, the active ingredient must be present in her/his product solely as a result of her/his incorporation into her/his product (during formulation or packaging) of a manufacturing-use product containing that active ingredient registered under FIFRA and purchased from another producer. The object of this provision is to simplify data compensation by making compensation for the generic data on the active ingredient an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the active ingredient in her/his product is being purchased from a firm which is required to submit (or to offer to share in the cost of obtaining) the generic data required by this Notice.

If a registrant who is subject to this Section 3(c)(2)(B) Notice fails to comply with the data submission requirement, the Administrator may suspend her/his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

1. the registration is for an end-use product, as opposed to a manufacturing-use product; and
2. the active ingredient in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of a manufacturing product which contains that active ingredient, is registered under FIFRA, and is purchased by the registrant; and
3. the registrant completes and executes a "Generic Data Exemption Statement" (Appendix IV-1) for the end-use products, and submits it to EPA within 90 days of receipt of this Notice; and

4. one or more registrants actually do undertake to submit; and do submit, all the data required by this Notice.

C. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The Pesticide Registration Guidelines,* or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD), which are yet to be published. If you wish to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may delete those uses at the time you submit your revised labeling for registration.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic-data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data which are required on each formulation, regardless of type of formulation. Product-specific data are further explained under Section V of this document and are specified in Tables B and C at the end of this Section.

D. Options Available for Complying with Requirements to Submit Data.

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" (Appendix IV-2) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. Attach a completed "Generic Data Exemption Statement" (Appendix IV-1).
2. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

* The Pesticide Registration Guidelines were proposed in two separate publications. On July 10, 1978, EPA issued proposed guidelines for product chemistry, environmental chemistry and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

3. Notify EPA you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must at the same time notify EPA which registrant(s) are parties to the agreement. At least one of the parties to the agreement must respond to this Notice.
4. File with EPA a completed "Statement of Willingness to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3*).
5. Request that EPA amend your registration by deleting the uses for which the data are needed.

* FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B) (iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

6. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

E. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. In the meantime, you must strive to meet the deadline for submitting the required data while EPA considers your request.

TABLE A
Generic Data Requirements for Products
Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition or Use Pattern	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Month and Year Data Due
163.61-3	Product Identity and Disclosure of Ingredients	Technical(T)	No		Yes ¹ /	2-83
163.61-4	Manufacturing Process Described	T	No		Yes	2-83
163.61-5	Discussion on Formation of Unintentional Ingredients	T	No		Yes	2-83
163.61-6	Certified Limits -Active	T	No		Yes	2-83
	-Impurities $\leq 0.1\%$	T	No		Yes	2-83
163.61.7	-Analytical Methods	T	Yes ¹ /	05007733 00006035 00005939	Yes	2-83
163.31-8	-Composition Data	T	Partial ² /	00006042	Yes	2-83
	Physical and Chemical Property Data:					
163.61-8(c)(1)	Color	T	No		Yes	2-83
163.61-8(c)(2)	Odor	T	No		Yes	2-83
163.68-8(c)(3)	Melting Point	T	No		Yes	2-83
163.61-8(c)(4)	Solubility	T	No ³ /		Yes	2-83
163.68-8(c)(5)	Stability	T	No ⁴ /		Yes	2-83

Note: Footnotes 1 through 10 are located immediately after tables.

TABLE A
Generic Data Requirements for Products
Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition or Use Pattern	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c) (2) (B)?	Month and Year Data Due
163.61-8(c) (7)	Physical State	T	Yes		No	
163.68-8(c) (8)	Density	T	No		Yes	2-83
163.161-1	Hydrolysis	All outdoor uses (other than around buildings)	Yes	00006058 05009322	No	
163.161-3	Photodegradation in Soil	All above-ground outdoor uses (other than around buildings)	No		Yes ^{5/}	12-83
163.162-1	Aerobic Soil Metabolism	All outdoor uses (other than around buildings)	No		Yes ^{5/}	12-83
163.162-3	Anaerobic Aquatic Metabolism	All above-ground outdoor uses (other than around buildings)	No		Yes ^{5/}	12-83
	Effects of Pesticides on Microbes	All outdoor uses (other than around buildings)	No		Undetermined ^{6/}	
	Activated Sludge Metabolism	All Uses	No		Undetermined ^{6/}	
163.81-1	Acute Oral Toxicity	All Uses	Yes	05019955	No	
163.81-2	Acute Dermal Toxicity	All Uses	Yes	00006030	No	
163.81-4	Eye Irritation	All Uses	Yes	00006028	No	
163.81-5	Skin Irritation	All Uses	Yes	00006029	No	

TABLE A
Generic Data Requirements for Products
Containing Zinc Phosphide

Guidelines Citation	Name of Test	Use Pattern	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Month and Year Data Due
-	Nature of the Residue	Outdoor Agricultural uses	Yes	00006047 00005999 05007787 05007791	No	
-	Analytical Methods	Outdoor Agricultural uses	Yes	05007791 00006044 05007610	No	
-	Residue Data: Raw Agricultural Commodities	Outdoor Agricultural uses		00006058 00006044 05005962	No	
163.71-1	1. Sugarcane		Yes	00006058	No	
	2. Vineyards		Yes	00006044	No	
	3. Rangeland Grasses		Yes	00005962	No	
163.71-1	Avian Single-Dose LD ₅₀	All Uses	Yes	00006031 00006025	No	
163.71-2	Avian Dietary LC ₅₀ Mallard Duck and Bobwhite Quail ^{7/}	All Uses	Yes	00006032 00006033	No	
163.71-3	Wild Mammal Toxicity	All outdoor uses (except around buildings)	No		Undertermined ^{8/}	

TABLE A
Generic Data Requirements for Products
Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition or Use Pattern	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Month and Year Data Due
163.71-4	Avian Reproduction	All above-ground outdoor uses (except around buildings)	No		Undetermined ^{8/}	
163.72-1	Fish Acute LC ₅₀ Rainbow Trout and Bluegill ^{7/}	All Uses	No		Yes	2-83
163.72-2	Acute Toxicity to Aquatic Inverte- brates ^{7/}	All uses	Yes		Yes	2-83
163.72-3	Acute Toxicity to Estuarine and Marine Organisms	Noncrop aquatic areas	No		Undetermined ^{8/}	
163.72-4	Fish Early Life- Stage Aquatic Invertebrate Life Cycle	Noncrop aquatic areas	No		Undetermined ^{8/}	
163.72-5	Fish Life-Cycle	Noncrop aquatic areas	No		Undetermined ^{8/}	
163.72-6	Aquatic Organism Accumulation	Noncrop aquatic areas	No		Undetermined ^{8/}	
163.70-1(d)	Reptile and Amphibian LC ₅₀ or Secondary Hazard	All outdoor uses (except around buildings)	No		Undetermined ^{8/}	
163.70-1(d)	Special Tests ^{9/}	All outdoor uses (except around buildings)	No		Yes	2-83

TABLE B
Product-Specific Data Requirements for Manufacturing-Use
Products Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Month and Year Data Due
163.61-3	Product Identity and Disclosure of Ingredients	Manufacturing-use (MU)	No		Yes ¹ /	2-83
163.61-4	Manufacturing/ Formulation Process Described	MU	No		Yes	2-83
163.61-5	Discussion on Formation of Unintentional Ingredients	Technical (T)	No		Yes	2-83
163.61-6	Certified Limits: -Active -Impurities >0.1%	T T	No No		Yes Yes	2-83 2-83
163.61.7	-Analytical Methods -Product Composition Data	MU MU	Partial ² / Partial ² /	05007733 00006035	Yes Yes	2-83 2-83
163.61-8(c)(1)	Color	MU	No		Yes	2-83
163.61-8(c)(2)	Odor	MU	No		Yes	2-83
163.61-8(c)(3)	Melting Point	T	No		Yes	2-83
163.61-8(c)(4)	Solubility	T	No ³ /		Yes	2-83
163.61-8(c)(5)	Stability	T	No ⁴ /		Yes	2-83
163.61-8(c)(7)	Physical State	T	Yes		No	2-83

TABLE B
Product-Specific Data Requirements for Manufacturing-Use
Products Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c) (2) (B)?	Month and Year Data Due
163.61-8(c) (8)	Density, and/or Density	MU	No		Yes	2-83
163.61-8(c) (12)	Storage Stability	MU	No		Yes	2-83
163.61-8(c) (13)	Flammability	MU	No		Yes	2-83
163.61-8(c) (14)	Oxidizing/Reduction	MU	No		Yes	2-83
163.61-8(c) (15)	Explosiveness	MU	No		Yes	2-83
163.61-8(c) (18)	Corrosion Characteristics	MU	No		Yes	2-83
163.81-1	Acute Oral Toxicity	MU	Yes	05019955	No	
163.81-2	Acute Dermal Toxicity	MU	Yes	00006030	No	
163.81-4	Eye Irritation	MU	Yes	00006028	No	
163.81-5	Skin Irritation	MU	Yes	00006029	No	

TABLE C
Product-Specific Data Requirements for End-Use
Products Containing Zinc Phosphide

Guidelines Citation	Name of Test	Composition ^{1/}	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Month and Year Data Due
163.61-3	Product Identity and Disclosure of Ingredients	End-use (EU)	No		Yes ^{1/}	2-83
163.61-4	Description of Manufacturing Process	EU	No		Yes	2-83
163.61-8(c)(1)	Color	EU	No		Yes	2-83
163.61-8(c)(2)	Odor	EU	No		Yes	2-83
163.61-8(8)(3)	Density	EU	No		Yes	2-83
163.61-8(c)(12)	Storage Stability	EU	No		Yes	2-83
163.81-1	Acute Oral Toxicity	Baits(B) < 2%	No		Yes	2-83
		Tracking Powder (TP) Yes		00005916(a)	No	
163.71-3	Wild Mammal Toxicity	Formulated bait	No		Undetermined ^{8/}	
163.72-5	Simulated and Actual Field Testing for Mammals & Birds	Formulated bait	No		Undetermined ^{8/}	
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	Formulated bait	No		Undetermined ^{8/}	

(a) These data have been submitted by Bell Laboratories, Inc., 3699 Kinsman Boulevard, Madison, WI 53704, and may be compensable.

FOOTNOTES

- 1/ Use "Confidential Statement of Formula" Form (EPA Form 8570-4).
- 2/ The Agency has acceptable analytical methodology for analyzing typical manufacturing-use products of zinc phosphide (see EPA's Manual of Chemical Methods and Devices); these procedures, if they are applicable, may be used to provide the composition data required by §163.61-7.
- 3/ Data are required for the solubility of zinc phosphide in common organic solvents.
- 4/ Data are required for the stability of zinc phosphide to metals, impurities (e.g., metallic ions) heat, and light.
- 5/ Use radiolabeled analytical grade or technical grade of active ingredient.
- 6/ The requirements for the submission of these data are currently reserved pending the review and modification of test protocols.
- 7/ Required on technical product.
- 8/ Depending on the results of other testing and the Environmental Fate Profile, these tests may be necessary in order to conduct a complete hazard assessment.
- 9/ Acute dietary toxicity to target species and whole body residue analysis (consult with EPA on protocol). These data are required to evaluate the potential for secondary risks to nontarget animals.
- 10/ Flammability data are normally required only for combustible liquids; however, because the technical zinc phosphide is classified as a flammable solid by the U.S. Department of Transportation, flammability data are needed for each manufacturing-use product.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA §3(c)(2)(B)

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to maintain the registration of your product(s). All these data must be submitted not later than 6 months after you receive this Guidance Document.

The tables entitled "Product-Specific Data Requirements for Manufacturing-Use Products" and "Product-Specific Data Requirements for End-Use Products," which appear as Tables B and C of this Guidance Document, permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)?"

In some cases the Tables may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, we encourage you to elect to cite that data in lieu of generating and submitting new data. (You must comply with FIFRA Section 3(c)(1)(D) if you elect to cite existing data; see Section III of this Guidance Document.)

VI. LABELING, CLASSIFICATION, AND PACKAGING INFORMATION

The Agency requires applicants for registration to amend their product's labeling to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application for reregistration, you must submit draft labeling revised to be consistent with: your product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.161, and labeling [40 CFR §162.1], as indicated by the following paragraphs this section of the Guidance Document. The labeling must be submitted within 6 months of your receipt of this Guidance Document.

If you fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel your registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. **PRODUCT NAME** - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. **NET CONTENTS** - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. **EPA REGISTRATION NUMBER** - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. **EPA ESTABLISHMENT NUMBER** - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. **INGREDIENT STATEMENT** - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the

product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40

CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity category I on the basis of oral, inhalation or dermal toxicity the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use with these statements surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h) (2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h) (2) (i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h) (2) (ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if the product meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

- a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.
- b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c) (13) (ii) of Subpart D.
- c. A "non-flammable aerosol" is one which meets the following criteria:
 - i. The flame extension is zero inches, using the method specified in 40 CFR §163.618(c) (13) (ii).
 - ii. There is no flash back; and
 - iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c) (13) (i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the item "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. **PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE** - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

As indicated in Chapter II of this document, the Agency has: (1) indicated certain formulations/uses to be restricted based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data, most of which has yet to be generated.

The required product-specific data should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix VI-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination and must be consistent with the terms of 40 CFR §162.10 and this guidance document with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the document should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of §162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.
2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:
 - a. Front panel statement of restricted use classification.
 - i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.
 - ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the administrator will define the appropriate wording for the terms of restriction by regulation.
3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:
 - i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.
 - ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are unrestricted from those that are RESTRICTED.
 - iii. You may register two separate products with identical formulations, one containing only unrestricted uses and

the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.
2. Restricted uses - The compliance schedule for restricted use products begins only after the approved label is returned to you as follows:
 - a. No product classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or product after the 120th day after the date of acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling. For the purposes of the first phase of reregistration, supplemental labeling means:
 - i. an adhesive sticker containing the restricted use statement specified in 40 CFR 162.10(j)(2) and also found in this section;
 - ii. a separate form containing the product name as it appears on the restricted use statement specified in 40 CFR §162.10(j)(2) and also found in this section; and
 - iii. the approved new label.
 - b. No product classified for restricted use under this first phase of reregistration may be distributed or sold by retailers or other persons after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling.
 - c. No product classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.
 - d. In cases where a registrant chooses to delete product uses classified as restricted under the first phase of reregistration, no such product may be released for shipment by the registrant or producer after the 180th day after acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

- e. No product classified as restricted under this first phase of reregistration may be advertised without including the restricted use classification after the 120th day after the acceptance of the label submitted in conjunction with your application.

Brochures, technical pamphlets and similar material which are in final printed form on the date of acceptance of the new label may be distributed only for 270 days from the date of acceptance.

Item 9c. MISUSE STATEMENT - The following statement is required on your label: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Appendix VI-I. [40 CFR §162.10(1)(2)(ii)]

Item 10A. RE-ENTRY STATEMENT - If there is a reentry statement for your product, that statement will be set forth in the second chapter of the Document.

Item 10B. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix VI-5 of the latest specific storage and disposal product labels.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-5. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which are referred to on the label or which are to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

C. Special (Child-Resistant) Labeling Requirements

As required in 40 CFR 162.16 (Appendix VI-6), any pesticide that is released for shipment by the registrant after March 9, 1981, must be in special packaging if:

- (1) its labeling permits residential use;
- (2) it has not been classified for restricted use; and
- (3) it meets the toxicity criteria of 40 CFR §162.16(c) (2).

Additional information on child-resistant packaging is being developed and will be mailed to you shortly.

VII. Instructions for Submission

All applications prepared in response to this Notice should be addressed as follows:

Product Manager
Phone No. (703)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

For each affected product for which continued registration is desired:

- A. Within 90 days from receipt of this package you must submit the FIFRA Section (3) (c) (2) (B) Summary Sheet (Appendix IV-2) with appropriate attachments.
- B. Within 6 months from receipt of this package you must submit:
 1. Application for Amended Pesticide Registration (EPA Form 8570-11).
 2. Confidential Statement of Formula (EPA Form 8570-4).
 3. Data Compensation Statement: Reregistration (Appendix III-1).
 4. Product-Specific Data Report (Appendix III-2).
 5. Two copies of any required product-specific data.
 6. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this Guidance Document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clearly indicate the front and side panels, and the intended type sizes of the text.
 7. A progress report on the development of generic mid-term and long-term data.

C. Within 24 months from the receipt of this package you must submit:

1. All required generic mid-term data (Table A).
2. A progress report on the development of generic long-term data (Table A).

D. Within 42 months from the receipt of this package you must submit the generic long-term data as committed (Table A).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

VIII. STATEMENT ON AGENCY POSITION REGARDING COURT SUITS INVOLVING FIFRA SECTION 3(c) (1) (D)

Several companies have sued EPA in an attempt to block implementation of FIFRA Section 3(c) (1) (D), which allows EPA to consider one firm's data in support of reregistration of another firm's product. EPA considers all available generic data in preparing a registration standard. If the companies are successful in the litigation, they could then use the reregistration process as a means of forcing competitors off the market. EPA does not intend to allow the reregistration requirement to be distorted in this fashion. If your application for reregistration would be affected by this litigation, you will receive instructions from EPA before the time your application must be submitted to EPA.

Appendix III-2

PRODUCT SPECIFIC DATA REPORT
Registration Standard for
Guidance Package Date:

EPA Registration No. _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (Check Below)	I am complying with Data Requirements by Citing Submittal MR ID Data (attached) (check box)	for EPA Use Only; Accession Numbers Assigned
-8(16)	Miscibility			
-8(17)	Viscosity			
-8(18)	Corrosion characteristics			
-8(19)	Dielectric breakdown voltage			
163.71-5(1)	Cage or pen field test			
-5(2)	Full-scale field test			
163.72-1	Fish acute LC ₅₀ - rainbow trout and bloodgill			
-1	Acute toxicity to aquatic invertebrates			
-2	Acute toxicity to aquatic invertebrates			
-3	Acute toxicity to estuarine and marine organisms			
-6(a) (1)	Short-term simulated field test			
-6(a) (2)	Long term simulated field test			
163.81-1	Acute oral toxicity			
-2	Acute dermal toxicity			
-3	Acute inhalation toxicity			
-4	Primary eye irritation			
-5	Primary dermal irritation			
-6	Dermal Sensitization			

Appendix III-2

PRODUCT SPECIFIC DATA REPORT
Registration Standard for
Guidance Package Date:

EPA Registration No. _____

Registration Guideline No.	Name of Test	Test not required for my product listed Above Check Below	I am complying with Data Requirements by Citing MR ID Submitting Data (attached) (check box)	for EPA Use Only; Accession Numbers Assigned
163.61-3	Product identity and disclosure ingredients			
-4	Description of manufacturing process			
-5	Discussion on formation of unintentional ingredient			
-6	Declaration and certification of ingredient limits			
-7	Product analytical methods and data			
163.61-8(1)	Color			
-8(2)	Odor			
-8(3)	Melting Point			
-8(4)	Solubility			
-8(5)	Stability			
-8(6)	Octanol/water partition coefficient			
-8(7)	Physical State			
-8(8)	Density or specific gravity			
-8(9)	Boiling Point			
-8(10)	Vapor Pressure			
-8(11)	pH			
-8(12)	Storage stability			
-8(13)	flammability			
-8(14)	Oxidizing or reducing action			
-8(15)	Explosiveness			

INDEX OF CITATIONS USED IN THE DATA REQUIREMENTS CHARTS
REFERENCES LISTED IN NUMERICAL ORDER

<u>MRID #</u>	<u>Author</u>
00005916	WARE Institute Incorporated (1978)
00005939	Elmore, J.W.; Roth, F.J. (1943)
00005962	U.S. Fish and Wildlife Service (1974)
00005999	Stephenson, J.B.P. (1967)
00006025	U.S. Fish and Wildlife Service (1977)
00006028	Piccirillo, V.J. (1977)
00006029	Piccirillo, V.J. (1977)
00006030	Piccirillo, V.J. (1977)
00006031	Matschke, G.H. (1978)
00006032	Matschke, G.H.; Higgins, W.H. (1978)
00006033	Matschke, G.H.; Higgins, W.H. (1978)
00006035	Hooker Chemical Corporation (1967)
00006042	Hooker Chemical Corporation (1967)
00006044	Lisk, D.J.; Smith, W.G.; Gutenmann, W. (1973)
00006047	Hilton, H.W.; Park, L.F.; Tesnima, A.H. (1972)
00006058	Hilton, H.W.; Robison, W.H.; Tesnima, A.H. (1971)
05007610	Okuno, I.; Wilson, R.A.; White, R.E. (1975)
05007733	Bellack, E.; Dewitt, J.B. (1952)
05007787	Hilton, H.W., Mee, J.M.L. (1972)
05007791	Robison, W.H.; Hilton, H.W. (1971)
05019955	Krishnakumari, M.K.; Muktna Bal, K.; Majumber, S.k. (1979)
05009322	Hilton, H.W.; Robinson, W.H. (1972)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

- 05007733 Bellack, E.; Dewitt, J.B. (1952) Procedure for the analysis of zinc phosphide rodenticides. *Journal of the Association of Official Agricultural Chemists* 35(4):917-920.
- 00005939 Elmore, J.W.; Roth, F.J. (1943) Analysis and Stability of Zinc Phosphide. *Journal of the Association of Official Agricultural Chemists* XXVI(4):559-564. (Also In unpublished submission received Sep 25, 1969 under OF0890; submitted by Hawaii, Dept. of Agriculture, Honolulu, Hawaii; CDL:093167-AB)
- 05007787 Hilton, H.W.; Mee, J.M.L. (1972) Studies with Radioactive Phosphine-32P in sugarcane. *Journal of Agriculture and Food Chemistry* 20(2):334-336.
- 00006047 Hilton, H.W.; Pank, L.F.; Teshima, A.H. (1974) Progress Report on Two Years of Rat Control with Zinc Phosphide Bait. (Technical supplement to insect and rat control report 24; unpublished study received Apr 16, 1973 under 10646-1; submitted by Hawaii, Dept. of Agriculture, Honolulu, Hawaii; CDL:005036-B)
- 00006058 Hilton, H.W.; Robison, W.H.; Tesnima, A.H. (1971) Fate of Zinc Phosphide and Phosphide in or near Sugarcane Fields. Includes undated method. (Unpublished study including 22 letters dated Jul 19, 1968 from H. W. Hilton to Plantation Agriculturalists, received mar 3, 1971 under OF0890; prepared by Hawaiian Sugar Planters' Association in cooperation with U.S. Dept. of Interior, Denver Wildlife Research Center, submitted by Hawaii Dept. of Agriculture, Honolulu, Hawaii; CDL:093187-A)
- 00006035 Hooker Chemical Corporation (1967) An Alternative Method for the Indirect Assay of Zinc Phosphide. Method dated March 21, 1967. (Unpublished study received Mar 22, 1976 under 12455-16; submitted by Bell Laboratories, Madison, Wis.; CDL:224561-A)
- 00006042 Hooker Chemical Corporation (1967) Zinc Phosphide--Data Sheet No. 809-A. (Unpublished study received Mar 1, 1972 under 935-11; CDL:022052-A)
- 05019955 Krishnakumari, M.K.; Muktna Bal, K.; Majumber, S.K. (1979) Evaluation of Acute Oral Toxicity of Zinc Phosphide on Rattus norvegicus (albino). *Pesticides* 13(11):33-35.
- 00006044 Lisk, D.J.; Smith, W.G.; Gutenmann, W. (1973) Phosphine Residues in Grapes Resulting from Vineyard Treatment with Zinc Phosphide. (Unpublished study including letter dated Jul 11, 1974 from D.J. Lisk to Richard Guest, received Sep 20, 1974 under 5E1551; prepared by Cornell Univ., Food Science Dept., Pesticide Residue Laboratory; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:094602-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHYCitations Considered to be part of the Data Base Supporting
Registrations Under the Standard

- 00006031 Matschke, G.H. (1978) A Zinc Phosphide Dietary LC₅₀ Study against Bobwhite Quail. (Unpublished study received Mar 28, 1978 under 6704-78; submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:233339-A)
- 00006032 Matschke, G.H.; Higgins, W.H. (1978) Adult Bobwhite Quail LD₅₀ and 95 Percent Confidence Limits. (Unpublished study received Mar 15, 1978 under 6704-78; submitted by U.S. Dept. of Interior Fish and Wildlife Service, Washington, D.C.; CDL:233243-A)
- 00006033 Matschke, G.H.; Higgins, W.H. (1978) Adult Mallard Duck LD₅₀ and 95 Percent Confidence Limits. (Unpublished study received Mar 15, 1978 under 6704-78; submitted by U.S. Dept. of Interior Fish and Wildlife Service, Washington, D.C.; CDL:233243-A)
- 05007610 Okuno, I.; Wilson, R.A.; White, R.E. (1975) Determination of Zinc Phosphide in Range Vegetation by Gas Chromatography. Bulletin of Environmental Contamination and Toxicology 13(4):392-396.
- 00006030 Piccirillo, V.J. (1977) Final Report: Acute Dermal Toxicity Study in Rabbits: Project No. 419-134. (Unpublished study reviewed April 12, 1977 under 6704-78; prepared by Hazleton Laboratories America, Inc. submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:229306-D)
- 00006028 Piccirillo, V.J. (1977) Final Report: Acute Eye Irritation Potential Study in Rabbits: Project No. 419-134. (Unpublished study reviewed April 12, 1977 under 6704-78; prepared by Hazleton Laboratories America, Inc. submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:229306-B)
- 00006029 Piccirillo, V.J. (1977) Final Report: Primary Skin Irritation Study in Rabbits: Project No. 419-134. (Unpublished study reviewed April 12, 1977 under 6704-78; prepared by Hazleton Laboratories America, Inc. submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:229306-C)
- 05007791 Robison, W.H.; Hilton, H.W. (1971) Gas Chromatography of Phosphide Derived from Zinc Phosphide in Sugarcane. Journal of Agricultural and Food Chemistry 19(5):875-876.
- 00005999 Stephenson, J.B.P. (1967) Zinc Phosphide Poisoning. Archives of Environmental Health 15(July):83-88. (Also in unpublished submission received Apr 23, 1976 under 6704-78; submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:224029-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be part of the Data Base Supporting
Registrations Under the Standard

- 00005962 U.S. Fish and Wildlife Service (1974) Black-Tailed Prairie Dog: Occurrence and Range. (Unpublished study received on inknown date under 4F1494; submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:093969-A)
- 00006025 U.S. Fish and Wildlife Service (1977) A Zinc Phosphide Dietary LC_{50} Study against Bobwhite Quail and Mallard Ducks. (Unpublished study received Jul 15, 1977 under 6704-78; submitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:230884-A)
- 00005916 WASF Institute, Incorporated (1978) Report: Analysis or Zinc Phosphide Assay: WARF Institute No. 8012728. (Unpublished study including letter dated Mar 14, 1978 from E.F. Marshall to William H. Miller, received Mar 16, 1978 under 12455-16; submitted by Bell Laboratories, Madison, Wis.; CDL:233398-A)
- 05009322 Hilton, H.W.; Robison, W.H. (1972) Fate of Zinc Phosphide and Phosphine in the Soil-Water Environment. Journal of Agriculture Food Chemistry 20(6) 1209-1213.

DATA COMPENSATION STATEMENT: REREGISTRATION

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address _____

Date of application for reregistration: _____

Registration Standard for products containing: _____

Date Reregistration Standard Issued: _____

Date Reregistration Guidance Document Issued: _____

In connection with applicant's application for reregistration under the Registration Standard and Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c) (1) (D) and 3(c) (2) (D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Registration Standard and Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product (taking into account the product's composition and formulation category and the uses its label will permit); and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application.

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated: _____

Name of registrant's
authorized representative:

(signature)

(typed)

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____
Registrant's Name: _____

As an authorized representative of the registrant of the product identified above, I hereby certify that:

- (1) I have read and am familiar with the terms of a Notice in a Guidance Document from EPA dated _____ concerning a requirement for submission of generic data on the active ingredient _____ under FIFRA Section 3(c) (2) (B).
- (2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product and it contains the active ingredient solely as the result of the incorporation into the product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.
- (3) An accurate confidential formula statement for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient in my firm's product. My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.
- (4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertaking made in this statement, my firm's product registration may be suspended in accordance with FIFRA Section 3(c) (2) (B).

Dated: _____

Registrant's authorized
representative:

(signature)

(Typed)

FIFRA 53(C) (2) (3) SUMMARY SHEET

EPA Product Registration No: _____
Product Name: _____
Applicant's Name: _____
Registration Standard for Products Containing: _____
Data Guidance Document Issued: _____

With respect to the requirement to submit "generic" data imposed by the FIFRA Section 3(c) (2) (B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ Attached is a completed "Generic Data Exemption Statement."
2. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Groups, OECD Chemicals Testing Programme, I enclose the protocols that I will use:
3. ☐ I have entered into an agreement with one or more other registrants under FIFRA §3(c) (2) (B) (ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).
4. ☐ I enclose a completed "Statement of Willingness to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:
5. ☐ I request that you amend my registration by deleting the following uses:
6. ☐ I request voluntary cancellation of the registration of this registration of this product.

Dated: _____

Registrant's authorized
representative:

(signature)

(Typed)

STATEMENT OF WILLINGNESS TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA

- (1) I am duly authorized to represent the following firms(s) who are subject to the requirements of a Notice under FIFRA Section 3(c) (2) (B) contained in a Guidance Document dated _____ to submit data concerning the active ingredient _____:

Name of Firm

EPA Company Number

(This firm or group of firms is referred to below as "my firm.")

- (2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:
- (3) My firm has offered in writing to enter into such an agreement, and has offered to be bound by an arbitration decision under FIFRA Section 3(c) (2) (B) (iii) if agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm

Date of Offer

However, none of those firm(s) accepted my offer.

- (4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c) (2) (B).

Dated: _____

(signature)

(Typed)

TABLE D

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SIMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL REQUIRED		COMMENTS
1	Product Name	All Products	Front panel	Center front panel	
2	Company Name	All Products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "packed for..." "Distributed by..." etc.
3	Net Contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Est. No.	All Products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All Products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statement	All Products	Front Panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front Panel Precautionary Statements	All Products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.

TABLE E

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
7A	Keep Out of Reach of Children (Child-Hazard Warning)	All Products	Front panel	Above signal word	Must type size requirements.
7B	Signal Word	All Products	Front panel	Immediately below Child Hazard Warning	Must type size requirements.
7C	Skull & Crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or Inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral Statement	All products where precautionary labeling appears on other than front panel	Front panel		

TABLE F-1

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
8	Side/Back Panel Precautionary Statements	All Products	None	Top or side of back panel preceding Directions for use	Must be grouped under the headings in BA, 8B, and 8C, preferably blocked.
8A	Hazards to Humans and Domestic Animals	All Products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental Hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or Chemical Hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted Block	All restricted products	Top Center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse Statement	All products	Immediately following Statement of Classification or ahead of Directions for Use		
10A	Re-entry Statement	All Cholinesterase Inhibitors	In the Directions for Use	Immediately after Misuse Statement	

TABLE F-2

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
10C	Storage and Disposal Block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of Directions for use	Must be grouped together and preferably blocked. Heading must be same type size as Child Hazard Warning.
10D U.S.	Directions for Use	All Products	None	None	May be in metric units as well as U.S. units.

Physical - Chemical HazardsCriteriaRequired Label StatementI. Pressurized Containers

A. Flashpoints at or below 20°F; or if there is a flashback at any valve opening.	Extremely Flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20° and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. <u>ALL OTHER PRESSURIZED CONTAINERS.</u>	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.

II. Non-Pressurized Containers

A. Flashpoint at or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Above 150°F	None Required

PROPOSED DISPOSAL STATEMENTS
FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all)

Do not reuse empty container (bottle, can, bucket).
Wrap (container) and put in trash collection.

2. Metal (all sizes)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local procedures.

4. Glass (all)

Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

Dispose of liners according to approved Federal State or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused,* dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

6. Paper and plastic bags

Dispose of bags according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

PROPOSED DISPOSAL STATEMENTS
FOR PESTICIDES

6. Paper and plastic bags

Dispose of bags according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).

PROPOSED DISPOSAL STATEMENTS
FOR PESTICIDESPESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL1. Household (all)

Do not reuse empty container (bottle, can, bucket).
Wrap (container) and put in trash collection.

2. Metal (all sizes)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local procedures.

4. Glass (all)

Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

Dispose of liners according to approved Federal State or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused,* dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

6. Paper and plastic bags

Dispose of bags according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.